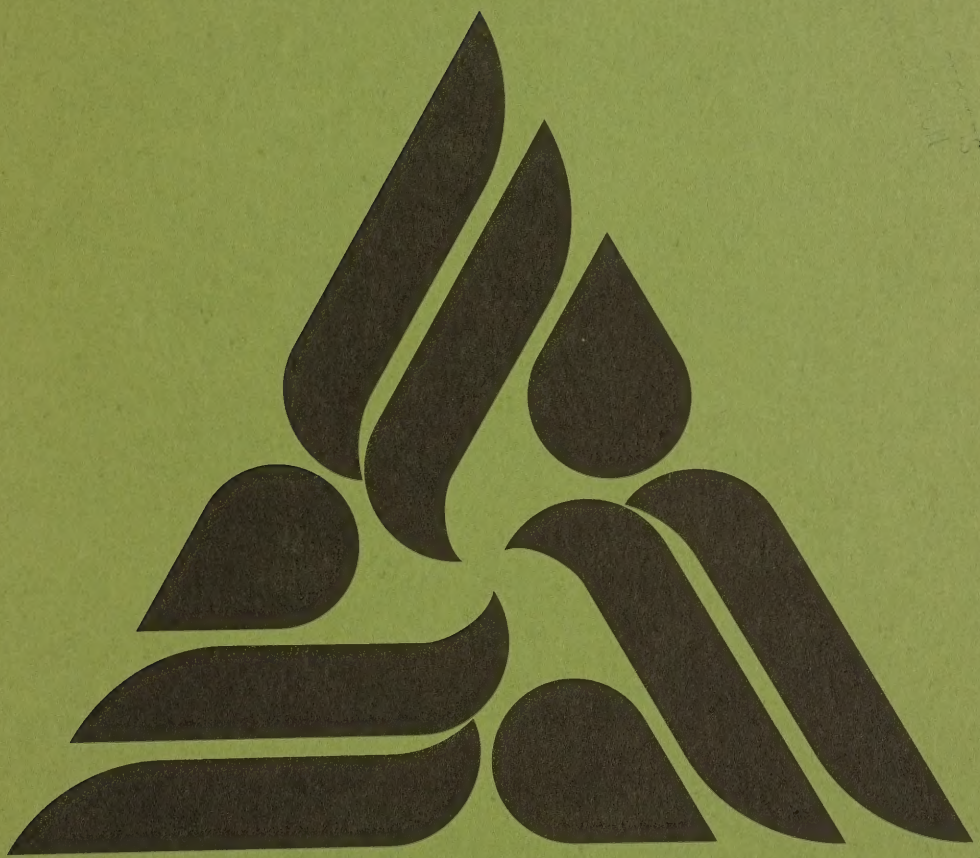
Office of
Agricultural
Biotechnology

# Minutes

## Agricultural Biotechnology Research Advisory Committee

June 23-24, 1988



Document No. 88-02

# U.S. DEPARTMENT OF AGRICULTURE

# AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE

# MINUTES OF MEETING

# JUNE 23-24, 1988

## CALL TO ORDER

Dr. Bennie Osburn, Chair, convened the second meeting of the Agricultural Biotechnology Research Advisory Committee (ABRAC) on June 23, 1988 at 9:10 a.m. in Room 104-A of the U.S. Department of Agriculture (USDA) Administration Building, 14th and Independence Avenue S.W., Washington, D.C. The meeting was open to the public.

Members present included:
Bennie Osburn (Chair), University of California, Davis, CA; George Hill, Meharry Medical College, Nashville, TN; John Gorham, Agricultural Research Service/Washington State University, Pullman, WA;
Ann Sorensen, American Farm Bureau Federation, Park Ridge, IL; Fred Gould, North Carolina State University, Raleigh, NC;
Frank Whitmore, Ohio State University, Wooster, OH;
Nicholas Frey, Pioneer Hi-Bred International, Des Moines, IA;
John Kemp, New Mexico State University, Las Cruces, NM;
Sue Tolin, Virginia Polytechnic Institute and State University, Blacksburg, VA;
Rodney Bothast, Agricultural Research Service, Peoria, IL;
Edward Korwek, Hogan and Hartson, Washington, DC;
Anne Hollander, The Conservation Foundation, Washington, DC;
Linda Phaire-Washington, Tuskegee Universtiy, Tuskegee, AL;
Alvin Young (Executive Secretary), USDA Office of Agricultural Biotechnology.

The roster of members present is included as Appendix A.

USDA Office of Agricultural Biotechnology (OAB) staff present included: Alvin Young, Daniel Jones, Marti Asner, Michael Olexa, Eva Russnak, Elsie Brown, Althaea Langston, Graham Purchase, Fred Kuchler, and David MacKenzie.

Others present included:

Paul Stern, University of Florida
Edward Raleigh, E.I. DuPont de Nemours & Co.
Cheryl Christensen, USDA Economic Research Service
Eugene Lomat, USDA Economic Research Service
Joseph O'Brien, University of Minnesota
Luther Williams, National Institutes of Health
Frank Serdy, Monsanto Co.
Jane Rissler, National Wildlife Federation

Pamela Love, USDA Cooperative State Research Service
Stacey Frost, USDA Cooperative State Research Service
Betty Ollila, USDA Office of the General Counsel
Lisa Grove, Office of Management and Budget
Roger Smith, New Jersey Department of Environmental Protection
Rudy Wodzinski, University of Central Florida
John Irwin, National Institutes of Health
T. Ross Wilkinson, North Dakota State University
Jacqueline Gallagher, Diversity
Olivia Bae, Tuskegee University
Alan Goldhammer, Industrial Biotechnology Association
Morgan Bockius, Washington, DC
Ken Snyder, National Audubon Society
Janet Shoemaker, American Society for Microbiology
James Maryanski, Food and Drug Administration
Bruce Umminger, Department of State
Ariel Hollinshead, George Washington University
Masami Semizu, Japan Economic Journal
John Keegan, Theseus Research
Alan Coffey, Theseus Research
Ann Dixon, Office of Management and Budget

**APPROVAL OF AGENDA**

Dr. Osburn recommended that the agenda as distributed be followed with the exception that Item VI, Research Guidelines, would follow Item VII, Other Business (Appendix B).

**APPROVAL OF MINUTES FOR MARCH 23-24, 1988 MEETING**

Members expressed the view that the minutes of the March 23-24, 1988 meeting were incomplete and lacked substance. Dr. Young explained some of the difficulties in preparing the first set of minutes. After some discussion, Dr. Osburn summarized the sense of the Committee to table approval of the minutes until the next meeting in order to give OAB time to prepare more substantive minutes.

**APPROVAL OF OPERATIONAL PROCEDURES**

Dr. Young presented the draft operational procedures to the Committee (Handout No. 15). The Committee recommended the following changes in the operational procedures:

Item 2 -- Development of Agendas. Amend to read "The public may submit suggestions for the agenda to the Executive Secretary or to the Chair."

Item 3 -- Announcements of Meetings. Amend to include, "Announcement of meetings of working groups requires publication in the Federal Register at least 15 days prior to their meetings."

Item 5 -- Pre-meeting Informational Materials. Amend to read, "In general, correspondence to the USDA that relates to ABRAC or its function will be provided to the ABRAC members and alternates in a timely manner. Material may also be obtained by the public for the ABRAC meetings, following the announcements in the Federal Register."

Item 7 -- Voting. Amend to read, "A majority shall be the majority of those present."

Item 11 -- Priority of Speaking. Amend to read, "Departure from such priority order may be made at the Chair's discretion."

Item 12 -- Conflicts of Interest and Appearances of Conflict. Ms. Hollander requested USDA to provide specific criteria for conflict of interest. Dr. Young said that there are no Department-wide criteria for conflict of interest, but some individual agencies may have them. Space for this item was reserved in the operational procedures pending possible revision and approval.

Item 13 -- Recording of Minutes. Amend to add, "Minutes will be taken at all closed meetings."

Item 14 -- Preparation of Minutes. Amend to delete, "from the written transcript."

Item 15 -- Public Information. Amend to substitute in the middle, "In the absence of the Chair, the co-chair or his or her designee will serve as media spokesperson." and to delete, "the Executive Secretary."

Dr. Korwek expressed the view that this item could not be adopted until the issue of communication among members and alternates had been addressed. Dr. Osburn suggested that item 15 be tabled for further discussion.

Item 17 -- Notice of Meetings. Amend to read "prepare the standard notice and include closed session."

A member moved to adopt the operational procedures under items 1, 2, 3, 5, 6, 7, 11, 13, 14, 17 and 18. The vote was 13-0 in favor of adoption. The Committee deferred on adoption of other items of operational procedure until after the responsibilities of ABRAC had been discussed.

**RESPONSIBILITIES OF ABRAC**

Dr. Young read the responsibilities of ABRAC from the charter (Handout No. 14). There was a major discussion on the contents of the charter as written and its intent with relation to the guidelines. Items discussed were as follows:

Dr. Gould expressed uncertainty about the scope of some of the language in the charter relating to biotechnology programs and policies. Dr. Young replied that the ABRAC is strictly an advisory committee, but it has wide latitude as long as its advice relates to biotechnology and is germane to agricultural research.

Members expressed the view that the role of ABRAC with regard to the review process should be spelled out clearly, not necessarily in the charter, but in the guidelines. In their view, the role of the IBCs, the review processes and acknowledgement of reviews by regulatory agencies should also be spelled out in the guidelines and not in the charter.

Dr. Tolin asked if there was any procedure for amending the charter upon ABRAC advice or if that was outside the purview of the Committee. Dr. Young replied that the Secretary would consider a recommendation made by the Committee to the Assistant Secretary to amend the charter; however, if the amendment involved changing the purpose of the Committee that would be a much larger issue and would likely invoke the exercise of wider authority.

Dr. Korwek observed that the charter is the enabling document that provides the authority under which the committee will operate, and it was designed to be broad, in order to give the Committee latitude.

Members discussed the relative timing of research reviews for scientific merit and biological safety. Dr. Williams of the National Institutes of Health (NIH), stated that if the ABRAC intends to follow the NIH model, that reviews for scientific merit and biological safety would be separate. Dr. Young elaborated that the funding agency could make adherence to biological safety guidelines a condition for accepting USDA research funds.

**OPERATIONAL PROCEDURES** (continued after discussion of ABRAC responsibilities)

Item 4 -- Attendance and Participation by Alternates at Full ABRAC Meetings. After consultation with OAB staff, Dr. Young recommended, "Members will ordinarily attend meetings, exercise voting privileges and receive reimbursement for their services. If a member is unable to attend a particular meeting, his or her alternate may attend the meeting in place of a member. Alternates may exercise voting privileges and receive reimbursement only if they are substituting for a member at a full ABRAC meeting."

Ms. Hollander and Dr. Korwek had earlier questioned the basis for the statement in the operational procedures that "Reviewers will not communicate with each other concerning information under review." Dr. Young explained this provision as an initially conservative position intended to stem the flow of information outside the Committee that might be regarded by some as violations of the Federal Advisory Committee Act. Subsequent discussions with the USDA Office of the

General Counsel (OGC) indicated that OGC regarded communications among reviewers as largely a policy matter that OAB could resolve in consultation with the ABRAC. Based on the Committee discussion, Ms. Hollander moved to change the wording under items 9 and 10 by deleting the sentence "Reviewers will not communicate with each other concerning information under review."

Item 8 -- Primary Reviewers. Dr. Young recommended revision to read, "If an issue or a proposal before the Committee requires expertise that is present on the Committee, the Chair will designate a primary reviewer or reviewers from the Committee members or alternates. Primary reviewers will be responsible for reviewing assigned material and reporting the results of the review to the full Committee. When an alternate serves as a primary reviewer at an ABRAC meeting, where the principal member is present, the alternate will serve as a consultant." This provides participation by alternates which allows coverage of their expenses, but does not give them a vote unless they are substituting for a member.

Item 9 -- Mailout Reviewers. Dr. Young recommended deletion of the sentence "Outside reviewers will not communicate with each other." He also raised the issue of whether specific identification of reviewers in material submitted to ABRAC might discourage outside reviewers from total frankness or even from participation in the review process.

Dr. Tolin suggested that if ABRAC is going to set up an open procedure, it should be entirely open. If ABRAC is going to conduct open and public reviews of research proposals, then witholding names of reviewers would not be very open. She reminded the Committee that the in the case of outside reviews for the NIH RAC, every letter is submitted to RAC and entered as a public document with the name of the person who is making the comments on that letter.

Dr. Rissler, of the National Wildlife Federation, said it is important to know who the reviewers are; the public wants to be assured that the research is safe and part of that assurance comes from the quality of review. The quality of review is dependent upon the quality of the reviewer and the names of reviewers would determine the degree of expertise.

Ms. Hollander expressed the view that ABRAC members are identified when they make statements of opinion and that outside reviewers should be held to the same standard of accountability. Dr. Gorham suggested that outside reviewers should be informed before they conduct a review that they will be identified along with their reviews. In view of the sense of the Committee, Dr. Young committed OAB to informing reviewers in the initial letter to reviewers that their comments will be made public along with their names.

Committee members expressed dissatisfaction with the term "mailout reviewers" and suggested that they be referred to as "external reviewers" instead.

Item 10 -- Working Groups. Amend to read, "The Chair may appoint working groups from among ABRAC members, alternate members, and other outside experts to address topics and issues relevant to ABRAC business. The OAB will furnish the relevant information to the working group members."

Item 15 -- Public Information. Amend to read, "The chair, co-chair or persons designated by them may serve as media spokespersons for the ABRAC. ABRAC members and alternates may not at any time discuss confidential business information with anyone outside the Committee, including media representatives."

Item 19 -- Modifications of ABRAC Operational Procedures. Add new item 19 stating that "The Committee's operational procedures can be modified by a majority of the members of the Committee at an ABRAC meeting."

The Committee voted 13-0 in favor of adopting items 4, 8, 9, 10, 15, and 19 as amended as Committee operational procedures. [The amended Committee operational procedures are attached as Appendix C.]

Item 12 on conflicts of interest and Item 16 on confidential business information were placed on hold pending OAB followup, possible revision, and Committee approval.

**OTHER BUSINESS**

**Receipt of Auburn Transgenic Fish Proposal**. Dr. Michael Olexa of OAB reported that USDA had received for review, a proposal from Auburn University for outdoor experiments on transgenic fish. At the time the proposal was received ABRAC membership had not been finalized and no procedures were in place. Based on this, OAB made the decision that an outside review was needed. OAB identified eight experts and asked each of them to review the proposal for biosafety. To date four responses have been received. After all of the responses have been received, OAB plans to extract comments from the responses and submit them to Auburn for its consideration. When Auburn submits information sufficient for an environmental assessment, the Auburn request will be placed on the ABRAC agenda.

Dr. Phaire-Washington suggested that ABRAC review of the Auburn proposal may be premature since the USDA research guidelines have not been solidified. Dr. Rissler of the National Wildlife Federation asked if Auburn is required to submit its proposal to ABRAC for a safety review. Dr. Young replied that as things stand now, one would interpret that Auburn must submit its proposal for review.

**Status of Research Handbook**. Dr. Graham Purchase of OAB reported on the status of the research handbook. The handbook is intended to supplement the research guidelines with more specific information of direct utility to researchers. Both the handbook and the guidelines will be published in the Federal Register for public comment. OAB has

prepared an outline of the handbook. The outline includes sections on containment, guidelines, regulations, non-scientific considerations, and roles and responsibilities of USDA, the institution, and the principal investigator. Individual sections have been assigned to various authors and writing will probably start immediately.

**Status of NBIAP**. Dr. David MacKenzie of OAB described the status of the National Biological Impact Assessment Program (NBIAP) to the Committee. NBIAP is essentially an activity of the Cooperative State Research Service (CSRS) that has been established with modest funding to begin the process of serving the needs of science and agricultural biotechnology, particularly in reference to field testing organisms.

Dr. MacKenzie indicated that there are three basic areas that NBIAP will be addressing: 1) surveillance of releases into the environment, including formation of a national surveillance network to monitor releases and assure that they do what they are expected to do; 2) establishment, maintenance, and sharing of information databases relative to organisms released into the environment; this information would be available not only to the scientific community but in particular to the Federal agencies that have the responsibility for regulation and oversight; and 3) answering many of the questions that deal with how to test organisms safely in the environment. The intent is to use NBIAP as a support mechanism for the biosafety activities of ABRAC. Dr. MacKenzie announced that as of September 1, he plans to begin a temporary appointment in Washington in order to work full time with NBIAP in getting it established.

**Other Business**. Dr. Daniel Jones of OAB informed the Committee of three letters to the Secretary of Agriculture that concerned ABRAC. The letters were from the Industrial Biotechnology Association, the Association of Biotechnology Companies and the president of Calgene. The letters concerned the administrative mechanisms at USDA for reviewing the safety of agricultural research involving new biotechnologies, and they expressed particular reservation about the mission and scope of the ABRAC.

Dr. Jones said that OAB is preparing replies to the letters which will be placed in the Committee record when they are approved. He said that copies of the incoming letters could be made available to the Committee now if the Committee so directs. Dr. Alan Goldhammer, IBA, indicated that even though their letter was addressed to Secretary Lyng, the intent was to have it distributed to ABRAC as a part of its deliberations for this meeting. The Committee requested copies of the three incoming letters and OAB distributed them to the Committee.

**Research Guidelines -- History**. Dr. MacKenzie of OAB summarized the history of the NIH and USDA research guidelines for the Committee. The current version of the USDA guidelines evolved from discussions between NIH and USDA in 1987 in which NIH incorporated portions of USDA generated information as Appendices P and Q of the NIH Guidelines on contained research on plants and animals, respectively.

USDA assembled the remainder of the information into draft guidelines relevant to agriculture. The document became so ponderous that the committee divided it into two parts, one containing information that is required to be published in the Federal Register, and the other in the form of a handbook of background and instructions for the scientists. The scaled-down version of the guidelines, reworked by the OAB staff, is currently before the Committee for its consideration.

These are intended to be guidelines to the scientific community for the process of scientific research, not the regulation of research. Products are regulated under existing rules and regulations by other agencies, but the Secretary of Agriculture is also responsible for assuring that agricultural research is conducted in a manner that is safe and not a threat to the environment or public health.

Committee members asked if there are written sources from which the Committee could obtain a more complete understanding of how the research guidelines developed up to this point. Dr. Young indicated that such information could be made available, but due to its volume, the committee may wish to consider how much information it could effectively absorb at one time.

Dr. Young described two different directions that the research guidelines could take. The first was promulgation as official rules or regulations. They would be published in the Code of Federal Regulations and there would be specific penalties for noncompliance. Revision of the guidelines in this form would require adherence to the Administrative Procedures Act. The second direction the guidelines could take is publication as a notice in the Federal Register with opportunity for public comment. Guidelines in this form would be easier to revise and research funding agencies could make adherence to the guidelines a condition for accepting USDA research funding. The Committee voted to support publication of the guidelines as a notice rather than a regulation by a vote of 12 in favor, 0 opposed, and 1 abstention.

Dr. Osburn asked the Committee to consider the possible scope of the USDA research guidelines, particularly in terms of the definition of biotechnology adopted and the range of techniques included. Dr. Tolin expressed the view that restricting the scope of the USDA research guidelines to recombinant DNA may not be adequate to assure the safety of agricultural research. In the years since the NIH Guidelines were established, she said, the number of ways in which scientists can manipulate the genomes of organisms has increased and some of the resulting genetic changes may need to be reviewed for biosafety. Ms. Hollander agreed, but raised the concern that definitions of biotechnology tend to be process-based whereas the National Academy of Sciences and other bodies have concluded that process should not be the determining factor in deciding what experiments should be reviewed for safety. She suggested another approach would be to consider whether

genetic material crosses certain biological boundaries in the transfer process.

## ABRAC WORKING GROUPS

Dr. Osburn requested that the Committee divide into three working groups for initial organizational meetings. The purpose of these initial meetings was to develop working group charges, identify necessary background information needed by the working groups, and select meeting dates for the first substantive meetings of the working groups. Dr. Korwek chaired the Definitions Working Group, Dr. Gorham chaired the Containment Working Group, and Dr. Tolin chaired the Guidelines Working Group.

The full Committee reconvened after the individual working group meetings. [Minutes of these meetings are attached as Appendix D, E, and F respectively.] Dr. Osburn asked each working group chair to report the results of his or her working group to the full Committee.

**Definitions Working Group**. Dr. Korwek reported that the first meeting of the Definitions Working Group (Definitions WG) is tentatively scheduled for July 28, 1988. Members are in the process of identifying informational materials that can be used to develop definitions. Dr. Korwek specifically requested that Dr. Thomas Wagner be added to the Definitions WG. He also discussed the possibility of inviting an EPA representative to participate because EPA is in the process of developing regulations in related areas. The Definitions WG defined its charge as developing working definitions for inclusion in the proposed USDA Guidelines for Research Outside the Laboratory. The working group discussed the definition of "biotechnology" and a number of members had deep reservations about generalizing this definition so much as to take in practically everything. The Definitions WG will rely on the Containment and Guidelines working groups for input on the usage and practical interpretation of the definitions it develops.

**Containment Working Group**. Dr. Gorham reported that the first meeting of the Containment Working Group (Containment WG) will be August 11-12, 1988. Background material for the meeting is either available or it will be sent. The meeting will be held in Washington, D.C. The Containment WG saw its charge as discussing and developing principles of biocontainment and bioconfinement for the USDA Guidelines on Biotechnology Research Outside the Laboratory.

**Guidelines Working Group**. Dr. Tolin reported that the first meeting of the Guidelines Working Group (Guidelines WG) will be in the last week of July in Washington, D.C. The Guidelines WG thought it was important to meet in conjunction with or very close to the time of the Containment WG, but also before August. In addition to Sue Tolin, Frank Whitmore and George Hill, the Guidelines WG suggested that Howard Hafs, Tom Wagner, and Steven Lindow serve as members of the group. The Guidelines WG also expressed interest in including Lois Miller and Anne Vidaver because of their involvement in the guidelines development

processes with NIH and USDA. The Guidelines WG saw its charge as developing a complete proposal of the USDA research guidelines.

Dr. Tolin indicated that the Guidelines WG will address the following points:

1. The group will go through each section and review it as currently written.

2. Section 100 will be primarily the responsibility of the Definitions WG, but the Guidelines WG will also review it.

3. Section 200, which describes various roles and responsibilities, will be primarily a responsibility of the OAB staff, but the Guidelines WG will review this section and discuss the appropriateness of the various statements.

4. Section 300 will be primarily the responsibility of the Containment WG, but the Guidelines WG will also review it in terms of the balance with Section 400, which is the Guidelines WG's primary responsibility.

5. Section 400 will be the classification of experiments into levels of review. The Guidelines WG plans to gather as many models as possible and discuss possible ways of categorizing them to set up a hierarchical system. Suggestions for categorizing were: 1) purpose-based; 2) trait-based; and 3) motility/risk-based. Dr. Tolin indicated that the Guidelines WG will consider first the classification of experiments pending in the NIH Guidelines, which is more or less an impact-based approach with plants and animals. It also includes genes that are added.

The Guidelines WG also discussed the concept of the handbook and thought it important to review the distribution of information between the guidelines and the handbook.

Dr. Young indicated some of the time constraints posed by the proposed meeting schedule. In order for the guidelines to be included on the agenda for the September 22-23, 1988 meeting, OAB will do its best to send the document to the Committee thirty days prior to the meeting. However, with the last working group meeting not occurring until the second week of August, it may be difficult to merge the Containment WG results into the document on time. The plan is to have a document emerging from the September meeting that could be published in the Federal Register for public comment.

Dr. Osburn asked Dr. Graham Purchase of OAB to describe his approach for reviewing the biosafety of organisms proposed for field testing. Dr. Purchase indicated that his approach addresses three main concerns: 1) whether the organism will cause harm or be pathogenic; 2) whether the organism is invisible to the unaided eye and therefore of potential concern as an unseen hazard; and 3) how motile the organism is. In the motility category there are three distinct possibilities: a) the

organism is sessile, i.e., either stationary or attached to something solid which does not move; b) the organism is passively motile, i.e., it moves around, but does not generally migrate from a distance; and c) the organism is actively motile, i.e., it has specific adaptations, e.g., wings, fins, etc., that enable it to move readily from one place to another. Dr. Purchase emphasized that his approach is equally applicable to all kingdoms of organisms be they plants, animals, microbes, or others.

Committee members had the following questions and comments on Dr. Purchase's approach to classifying experiments:

How would genetic manipulation fall into the different categories? One response was that a biosafety reviewer would ask whether the new trait confers a competitive advantage that makes the organism harmful.

There is some real benefit to this approach, but the harmful/not harmful dimension seems rather subjective. It may need more objective criteria in order achieve its maximum utility.

Dr. Tolin indicated that one point raised in the working group discussion was that the initial guideline proposal is more or less kingdom-based, i.e., grouped by plant, animal or microbe. One suggestion was that it could be trait-based or purpose-based and then combined with confinement levels.

**MEETING PLANS**

The next three meetings of ABRAC are scheduled for September 22- 23, 1988; January 5-6, 1989 and March 23-24, 1989. The meetings are tentatively scheduled to be held in the Williamsburg Room (Room 104-A, Administration Building) of the Department of Agriculture.

**ADJOURNMENT**

Dr. Osburn adjourned the meeting at 2:38 p.m., June 24, 1988.

Respectively submitted,

ALVIN L. YOUNG
Executive Secretary

BENNIE I. OSBURN
Chair

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE (ABRAC)
June 23-24, 1988

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ABRAC, June 23-24, 1988 (continued)

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# AGENDA

## AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE
## U.S. DEPARTMENT OF AGRICULTURE
Room 104-A, Administration Building
Washington, DC 20250

June 23, 1988 - 9:00 a.m.-5:00 p.m.
June 24, 1988 - 9:00 a.m.-3:00 p.m.

I. Call to Order

II. Approval of Agenda

III. Approval of Minutes for the March 23-24, 1988 Meeting

IV. Approval of Operational Procedures (Structure of Working Groups) (30 minutes)

V. Responsibilities of ABRAC

VI. Research Guidelines

- History
- Definitions
- Biocontainment Principles
- Levels of Review

VII. Other Business

- Receipt of Auburn Transgenic Fish Proposal
- Status of Research Handbook
- Status of NBIAP

VIII. Next Meeting - September 22-23, 1988

IX. Adjournment

# OPERATIONAL PROCEDURES FOR THE AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE (ABRAC)

June 24, 1988

## 1. Frequency of Meetings

ABRAC meetings will be held at approximately quarterly intervals, i.e., every three months, unless Committee business warrants a change in frequency. Meetings are held at the call of the Chair. The Executive Secretary may recommend specific dates for meetings. Proposed dates for the next three meetings are September 22-23, 1988, January 5-6, 1989, and March 23-24, 1989.

## 2. Development of Agendas

OAB will develop agendas for ABRAC meetings in consultation with the ABRAC Chair. Members or alternates may recommend agenda items to the Chair or Executive Secretary. Members of the public may also suggest agenda items to the Chair or Executive Secretary. Notice of major actions on the ABRAC agenda will be published in the Federal Register at least 30 days before the meeting at which they are discussed. Members of the public may submit written comments to the Chair or Executive Secretary in response to the Federal Register notice.

## 3. Announcements of Meetings

OAB will prepare announcements of full ABRAC meetings for publication in the Federal Register at least 30 days prior to the meeting. OAB will prepare announcements of ABRAC working group or ad hoc subcommittee meetings for publication in the Federal Register at least 15 days prior to the meeting. Shorter notice may be provided in special situations if the reasons for the special exception are made part of the meeting notice.

## 4. Attendance and participation by alternates at full ABRAC meetings

Members will ordinarily attend meetings, exercise voting privileges, and receive reimbursement for their services. If a member is unable to attend a particular meeting, his or her alternate may attend the meeting in place of the member. Alternates may exercise voting privileges and receive reimbursement only if they are substituting for a member at a full ABRAC meeting.

## 5. Pre-meeting informational materials

OAB will distribute pre-meeting informational materials to both

members and alternates in as timely a manner as possible. The primary mailing will be sent out at least 30 days in advance of a meeting, but additional mailings may be necessary in some instances. General correspondence concerning issues under ABRAC consideration will be made available to ABRAC members and alternates in a timely manner.

6. Rules of order

Standard rules of order such as Robert's Rules of Order may be used at the Chair's discretion. Departures from such standard rules of order may be made at the Chair's discretion.

7. Voting

Only members, including the Chair, and alternates substituting for members at a particular meeting may vote on issues before the Committee. The Executive Secretary will perform a quorum check at the beginning of each meeting to verify that at least 7 members are present and to determine which alternates are substituting for principal members and therefore entitled to vote at that particular meeting. A majority for voting purposes shall be a majority of the members present.

The Executive Secretary or his/her designee will be responsible for counting hand votes and recording them. For each issue on which a vote is taken, the minutes will show the number of votes for, votes against, and abstentions. If members so request, the minutes will identify them by name as members who cast votes for or against a particular issue. Members may submit minority opinions for inclusion in the minutes.

8. Primary reviewers

If an issue or proposal before the Committee requires expertise that is present on the Committee, the Chair will designate a primary reviewer or reviewers from the Committee members or alternates. Primary reviewers will be responsible for reviewing assigned material and reporting the results of the review to the full Committee. When an alternate serves as a primary reviewer at an ABRAC meeting at which his or her principal member is present, the alternate will serve as consultant entitled to reimbursement but not voting privileges.

9. External reviewers

If an issue or proposal before the Committee requires expertise that is not present among the Committee membership, OAB will, with the assistance of the National Biological Impact Assessment Program (NBIAP) or other resources, identify appropriate external reviewers. OAB will mail out the material to be reviewed to the external reviewers individually, receive the written reviews from the external reviewers individually, and assemble the reviews for subsequent ABRAC review. When the

issue or proposal is placed on the ABRAC agenda, review packages submitted to the ABRAC will identify the persons who developed the individual reviews.

10. Working Groups

The Chair may appoint working groups from among ABRAC members, alternates, and other experts to address topics and issues relevant to ABRAC business. The OAB Director will furnish relevant information to the working group members. Working group meetings will be announced and open to the public unless certain sessions are closed because confidential business information is under discussion.

11. Priority order of speaking

The Chair will determine the priority order of speaking on specific issues. The following generic order of speaking is recommended: 1) ABRAC members, 2) consultants, 3) OAB staff, 4) agency, committee, or organization liaisons to the ABRAC, 5) members of the audience who have submitted written comments, and 6) members of the general audience. The Chair may limit the time available to any speaker before the Committee.

12. Conflicts of interest and appearances of conflict

[Statement pending OAB revision and ABRAC approval]

13. Recording of meetings

All open sessions of ABRAC meetings will be recorded and a written transcript prepared by a commercial recording service. Closed sessions of ABRAC meetings will not be recorded and a transcript will not be prepared, but minutes will be prepared.

14. Preparation of minutes

The Executive Secretary or his/her designee will prepare draft minutes of ABRAC meetings. Minutes will be amended or approved by the full Committee, certified by the Chair, and signed by the Executive Secretary or his/her designee.

15. Public information

ABRAC members and alternates are encouraged to cooperate as fully as possible with representatives of the media. The Chair, Co-Chair, or a person designated by the Chair or Co-Chair may serve as a media spokeperson for ABRAC. ABRAC members and alternates may give interviews as requested if they wish. OAB requests that the OAB public affairs specialist be notified of such interviews in a timely fashion. ABRAC members and alternates may not at any time discuss confidential business information with anyone outside the Committee including media representatives.

16. Confidential business information

[Statement pending OAB revision and ABRAC approval]

17. Closed sessions

For a meeting or part of a meeting at which confidential business information is to be discussed, OAB will include an announcement of the closed session and the reasons for closing it in the Federal Register announcement of the meeting.

18. Adjournment authorities

Ordinarily, the Chair or his/her designee will adjourn meetings. However, if the Chair is a non-federal employee, the Executive Secretary shall have the authority and be required to adjourn any meeting under circumstances in which he/she considers adjournment to be in the public interest.

19. Modifications of ABRAC Operational Procedures

These operational procedures may be modified by a majority vote of the full ABRAC.

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UNITED STATES DEPARTMENT OF AGRICULTURE

AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE

WORKING GROUP ON DEFINITIONS

MINUTES OF THE MEETING

June 24, 1988

The Agricultural Biotechnology Research Advisory Committee (ABRAC) Working Group on Definitions (henceforth referred to as the Working Group) was convened for its first meeting on June 24, 1988 in Washington, D.C. Dr. Edward L. Korwek chaired the meeting. For a complete list of those present see Attachment I.

## I. CHARGE FOR THE WORKING GROUP

The Working Group agreed that it would meet for its next meeting on July 28, 1988 in Washington, D.C. July 26 or 27 would be alternative dates. This would allow enough time to develop definitions prior to the next ABRAC meeting in September, 1988.

Dr. Korwek opened discussions on the Charge for the Working Group. Dr. Alvin L. Young clarified that a general charge was necessary to announce the next Working Group meeting in the Federal Register and to help the Working Group define its focus.

Dr. A. Ann Sorensen asked if the Working Group had been given a list of

words that needed to be defined? Dr. Korwek answered that they had not; but the Working Group could select words to define from previous lists.

Ms. Anne K. Hollander proposed that the Working Group work from definitions already accepted by other United States government agencies. By consensus the Working Group agreed with this approach. Dr. Korwek agreed to assemble lists of definitions in use and to have the United States Department of Agriculture (USDA) Office of Agricultural Biotechnology (OAB) provide these lists to Working Group members prior to the next meeting.

Dr. Korwek proposed the following charge:

> "To develop working definitions to be used in the proposed USDA Guidelines for Research Outside the Laboratory."

The Working Group agreed to this Charge by consensus.

## II. MEMBERSHIP OF THE WORKING GROUP

Dr. Alvin L. Young explained that a list of members of the Working Group and alternatives had been provided, however, the Working Group could add members if they knew of experts who could contribute to the Working Group's deliberations.

The consensus was that Dr. Thomas E. Wagner, who had been an original Working Group member, be recontacted because of his expertise on transgenic

animals. It was also decided that the Environmental Protection Agency (EPA) be asked if they would be interested in providing a person familiar with definitions. Alternatively, the Working Group could use written material provided by EPA.

The Working Group considered the possibility of adding someone from the Agricultural Research Service (ARS). However, it was decided ARS had already had input in the definitions during earlier stages of developing the USDA Guidelines.

## III. DEFINITION OF THE PURPOSE OF THE GUIDELINES

Ms. Hollander proposed, "To specify (_____) practices and procedures for agricultural research outside the laboratory, not subject to review by other Federal agencies or the National Institutes of Health (NIH) Recombinant DNA Advisory Committee (RAC)."

Dr. Korwek suggested that the word "biotechnology" be added after "agricultural." Dr. Rodney J. Bothast asked if the Working Group needed to define "agricultural biotechnology?" Dr. Korwek and Ms. Hollander stated that these defintions would be developed by the Working Group later.

Dr. Korwek asked if "confinement" could be used to fill-in the blank in Hollander's proposed definition? Ms. Hollander replied the Guidelines spoke to other issues as well as confinement.

Dr. John D. Kemp and Dr. Sorensen stated their preference for keeping the definition simple. Dr. Kemp suggested "safe" in the blank. The Working Group agreed to this by consensus.

Dr. Kemp asked why Ms. Hollander had omitted "funded by USDA" from her proposed definition. Ms. Hollander replied, that by omitting this phrase it made it clear that non-USDA researchers may elect to follow the Guidelines on a voluntary basis. Dr. Korwek stated that adding "funded by USDA" would not prohibit others from following the Guidelines.

Dr. Sorensen stated that she favored adding "funded by USDA" to the definition because it would reassure the research community that they would not be subject to multiple reviews. Drs. Bothast and Korwek concurred with this approach. Ms. Hollander, after hearing these view, changed her position and advocated adding the phrase "funded by USDA" with the understanding that the ABRAC or other Working Groups might ask that it be modified at a later date. The majority of the Working Group agreed, however, Dr. Kemp dissented on this point.

Dr. Sorensen then proposed, "The purpose of the Guidelines is to specify safe practices and procedures for USDA funded biotechnology research that occurs outside the laboratory and it is not subject to review by other Federal regulatory agencies or the NIH-RAC."

The Working Group then discussed the phrase "is not subject to review." Dr. Korwek expressed concern that the phrase was vague and might cover courtesy reviews for purposes other than safety. Dr. Kemp stated that this

issue was related to the issue concerning USDA funding, i.e., that it raised questions for the scientist about requirements for duplicative review. By consensus the Working Group decided to leave the difinition as stated and to clarify it later in the Guidelines.

Dr. David R. MacKenzie proposed that the Working Group add a second sentence to the definition about the intent of the Guidelines. He proposed, "The purpose of the Guidelines is to avoid redundancy while providing for biosafety." The majority of the Working Group liked this proposal because it stated upfront the intent of the Guidelines.

Dr. Korwek suggested, "The intent of these Guidelines is to avoid redundancy in Federal oversight while providing adequate biosafety review of research."

Ms. Hollander and Dr. Bothast suggested substituting "duplicative Federal review" for "redundancy." Dr. MacKenzie suggested substituting "while assuring protection of public health and the environment" for "biosafety."

Dr. Kemp expressed concern that this would make the definition too broad and leave the ABRAC open to litigation. Dr. Korwek stated this was a real concern, but he didn't believe it would be a problem.

Dr. Sorensen read the complete, final proposed definition,

> "The purpose of the Guidelines is to specify safe practices and procedures for USDA-funded biotechnology research not subject to review by other Federal agencies or the NIH-RAC. The intent is to avoid duplicative Federal review, while assuring protection of public health and the environment."

The Working Group reached consensus that this was a good start, which would be clarified by other material later in the Guidelines.

## IV. DEFINITION OF BIOTECHNOLOGY

The Working Group discussed the OAB definition of biotechnology. Dr. Korwek and Ms. Hollander agreed that "non-classical" should be deleted from the OAB definition, thus making the definition very broad, with the understanding that the definition would probably be narrowed later by other exclusions specified in the Guidelines. Dr. Kemp disagreed with this approach, stating that he believed it would set ABRAC's responsibility to widely.

Other parts of the OAB definition were discussed, but no decisions were reached because of the lack of time.

The meeting was adjourned.

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APPENDIX E

Minutes of the Agricultural Biotechnology Research Advisory Committee, Containment Working Group, June 24, 1987

Present were John Gorham (Chairman), Nicholas Frey, Linda Phaire-Washington and Fred Gould.

Also in attendence were Mike Olexa, Graham Purchase and Pamela Love, Alvin Young, and Bennie Osburn.

Date of Next Working Group Meeting

The suggested date for the meeting was during the week of July 25 to July 29, 1988. Gorham and Frey indicated they could not attend and Washington and Gould probably could not attend a meeting during that time.

Young indicated that he wanted a draft of the working group report to be published in the Federal Register and that a period of thirty days notice was required for public comment. Young then suggested that the working groups could prepare drafts of the reports at the next meeting which could be circulated among the full ABRAC prior to the September meeting.

Osborne indicated there is a risk assessment symposium in Davis, California between the first and fourth of August, 1988. The date of the working group meeting was initially set for the fourth to fifth of August 1988 with Carlson, Lindow, Barbeito (Alternates, Thiermann and Moon) to be invited as consultants. Subsequently, this date proved unsuitable and the date of August 11-12, 1988 was selected. The meeting will be held in the Williamsburg Room, USDA, Washington, D.C. from 8 a.m. to 5 p.m.

Membership of Working Group

Frey suggested the working group should be six to seven people rather than nine to ten. There appeared to be general agreement on this.

Gould suggested that his alternate, Steven Lindow had a better knowledge of containment and should be present. Lindow is serving on the Environmental Protection Agency (EPA) containment committee which meets on July 15. The EPA committee also has a hydrologist and a specialist in spore containment on the committee. The role of the EPA committee and this working group overlap considerably.

Gorham felt that Witter was better qualified to serve on the committee. He suggested bringing in others in the animal area such as Yulma, who has experience on Rinderpest; Breeze from Plum Island; Thiermann; Moon, and Purchase.

Frey suggested Xavier Delaney who is a specialist in genetic engineering of plants, Steven Lindow and Peter Carlson who are alternates on the Agricultural Biotechnology Research Advisory Committee (ABRAC), and someone from Ciba Geigy.

Gould suggested Lorraine Hallowasch from Rohm Haas.

Gould suggested that the working group should have a representitive from EPA who are currently developing guidelines. The Office of Agricultural Biotechnology (OAB) should specifically invite someone from EPA.

Purchase suggested Manuel Barbeito.

Material to be Distributed

National Institutes of Health (NIH) guidelines, Animal Plant Health Inspection Service (APHIS) regulations in the Federal Register, the Office of Science and Technology Policy (OSTP) document, the EPA document, the NIH biocontainment handbook, McKenzie's outline, Purchase's outline. Washington indicated that the working group needed to have all the background material in order to do their homework.

Charge for the Working Group

Olexa suggested that the function of the working group is to discuss and develop the principles of biocontainment and bioconfinement for biotechnology research outside the laboratory. Gould suggested that it was important to take into consideration the ecology of each organism.

Discussion of Bioconfinement Section of the Guidelines

Purchase suggested that there could be at least two approaches. The first was to take the NIH guidelines as a start and make necessary revisons to make them applicable to agricultural biotechnology research outside the laboratory. The second approach was to start anew and ask, What are the most important principles for confinement outside the laboratory? How should experiments outside the laboratory be classified? and What kinds of experiments require approval? From this point of view, bioconfinement principles involve (a) the harm or potential harm (pathogenicity) that could be caused by the organism; (b) the size of the organism, that is whether it is macroscopic (gross) or microscopic; and (c) whether the organism is sessile, passively motile, or actively motile. Requirements for notification, review, and/or approval could be based on these properties.

H.G.P. 7/1/88

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APPENDIX F

# MINUTES
# AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE
# RESEARCH GUIDELINES WORKING GROUP

## June 24, 1988

Meeting Dates: July 25-26 or July 28-29--The Guidelines Working Group discussed the need to combine with other working groups on dates.

Charge: The charge for this working group is the classification of experiments and general format.

Approach: This group could concentrate on identifying with the other working groups the organisms or recombinant molecules and the levels of containment.

The goal when the three working groups have finished their meetings is to have a complete set of guidelines to be published as an agenda item for the September meeting.

This working group's primary responsibility is Section 400, which covers the scope and establishes the hierarchy and determines how it is to be presented. The original way it was presented was organism and level of review but not broken down into categories. A decision needs to be made as to whether to use the organism-based approach. It would be based on who reviews it, and this would be a proces base in that certain processes would be exempt from review, certain processes would be IBC or a combination, and certain ones would require ABRAC review. This is sort of a non-official classification based on the combination of process and politics. Neither are science-based--a more research-based approach was suggested. Tolin indicated that she would like to explore the consequence and worst-case scenario and not a risk-based approach. Tolin explained that it would be based on initial cross or initial modification has the greatest potential for having a consequence that would be detrimental, and in a small scale of research you would be more likely to have an organism that causes a problem than if you were at a later stage of the process after you had done a great deal of selection. This would then be more of a research-based approach and one that hasn't really been used and may be more fitting with agricultural research.

The purpose of the research with modified organisms is to see whether they could function in a natural environment--could they tolerate the conditions. This would be a very low-risk type of experiment but would require a decision be made as to why it was being put in the field. With regard to the transgenic fish proposal this perhaps would be a combination of testing--what it would do to the environment--would it compete more successfully

with its cohabitants in the field--this would appear to be a more hazardous type and would have to be backed by some kind of documentation. Dr. Whitmore agreed to write this up and send it to the chair of the working group to distribute to other members of the working group.

It was generally agreed that a new approach would be appropriate.

It was noted that there was no visible mechanism to extend the guidelines to involve the states in the review of the research that will be going on within the state. Tolin indicated that this could be worked through the IBC tie-in because the IBC would be approaching the local level. She indicated this was a good approach and there was no reason why the state agency could not be notified of an experimental field trial. She agreed to talk to the state people in how to bring in the local review.

The question was asked about the feasibility of basing it upon a trait instead of where you are in the research. You then are concentrating on the perceived or potential risks and the consequence of the trait. This is based very much on the science and is an approach which the public can accept.

The one charge that this committee, as a whole, needs to discuss and can be initiated in this working group is the ability to shift quality case-by-case to eventually a generic categorization.

Tolin reminded the group that they are formulating guidelines by which a researcher can proceed and conduct research and that includes not who reviews it but how the researcher conducts the research. In order to tie this together with the confinement or containment group there needs to be a description of what the lowest level, a standard practice, is.

The researcher needs to be able to determine the type of review, the type of study and the type of containment at each point in the research and then get general guidance from which to develop precise protocols to be followed. A decision would then have to be made as to where protocols need to be checked--should there be a track on it--should it be done for the lowest level of concern at the local level, state level or federal level.

Responsibilities of Working Groups

The question was asked which working group would be doing parts 100 through 300. The part that relates to definitions will be the Definitions Working Group. Part 300 is the containment or safety principles and that will be done by the Confinement Working Group. The Guidelines working group is essentially concerned with part 400 but will work closely with the containment group.

The group agreed they should discuss parts 100 and 200 even though some of this will be done by the definitions group and OAB staff. The main concern was that this group wants to assure that everything is covered.

The group discussed the Graham Purchase scheme--essentially based on if its small it's harder to contain and is more likely to be disseminated. There are basically three categories--the harmfulness of the trait, the size of the organism, and the means of dissemination. It was agreed that the most science based approach would have to be the potential risks or harmfulness.

Some points to consider:

1) Is the potential consequence really worth the bother to track it?

2) To tie in with confinement, the monitoring and tracking after release.

3) A categorization of how the experiment would be conducted--one could require very extensive monitoring and one could require very little--perhaps this is the type of categorization that could be worked out. An experiment with a potential high consequence would combine with extensive monitoring to monitor the effectiveness of the containment being a part of that.

Dr. Tolin indicated that if anyone had a proposal for a type of hierarchical system that could be established it would be appreciated and would be discussed at the working group meeting.

There was a discussion on types of documents they would be interested in reviewing: 1) Graham Purchase document. Parts of the Arlington House Workshop document which is a combination of classification experiments. There are some pieces that pertain to confinement, classification of experiments, how to submit an application, points to consider, etc.--some of these should be included in the Handbook.

It was agreed that the working group should bring up some of these things and specifically identify those that need to be expanded on in the Handbook.

There was concern that part 300 as current written went into great detail with exact examples and definitions of how to do things; whereas this document (the guidelines) should identify those areas that the researcher needs to be cognizant of and then provide the Handbook to give examples on how and let researchers develop their own protocol.

Do not want to get hung up on examples--however, the Confinement group may want their section more defined.

The Handbook would say how and the IBC and NBIAP will play an important role in local/geographic considerations.

It was asked if something on the Handbook would be available to the working groups. The group felt it was important to have some information on the handbook since in some cases they were deferring to the Handbook.

The primary section of focus for this working group is Section 400 as written. Section 200 would be done primarily by OAB staff; Section 100 is being done by the Definitions Group. It was agreed that OAB should take care of Section 200 but this group would review it at the meeting. Section 200 is where there is two sides as to what belongs in the guidelines and what belongs in the Handbook. There is a need to streamline who has to report what.

It was suggested that the Guidelines Working Group review Section 200 and have the NIH guidelines provided to the working group members so they can compare Section IV of the NIH guidelines to Section 200. The group needs to look at this to determine what level of detail is desired.

Documents Suggested:

1) The NIH Plant and Animal sections (Aug.11).
2) Parts of the Arlington House Workshop document.
3) Dr. Purchase's suggestion.
4) Current NIH Guidelines

The working group plans to have a proposal to include on the agenda for the September meeting. It was felt that the Guidelines group should meet in conjunction with and perhaps on the same days that the Confinement Group meets and perhaps after the Definitions group.

Membership:

Sue Tolin (Chair)
Tom Wagner
Lois Miller
Ann Vidaver
George Hill
Anne Hollander
Harold Hafs

Anne Hollander expressed an interest to work with the Definitions Group but indicated she would also like to be in attendance at the Guidelines working group meeting. Whether she's a formal member is up to OAB.



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